REMARKS

This paper is filed in response to the Office Action mailed May 26, 2006. Claims 1 to 76 are pending. Claims 10, 12 to 14, 21, 22 and 40 to 68 stand withdrawn for consideration as directed to a non-elected invention. Claims 5, 8, 9, 19, 20 and 32 have been cancelled herein without prejudice. Applicants maintain the right to prosecute the cancelled claims in any related application claiming the benefit of priority of the subject application. Accordingly, claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 are under consideration.

Regarding the Amendments

The amendments to the claims are supported throughout the specification or were made in order to address various informalities. In particular, the amendment to claims 1, 11, 15, 16, 29, 31, 34 to 39, 69 to 73 and 75 to recite an "antibody that specifically binds to OX40L" is supported, for example, by originally filed claims 9 and 20, and in the specification, for example, at page 6, lines 21-25, page 10, lines 27-30, page 12, lines 13-16, and page 17, lines 9-10. The amendment to claims 1, 15, 16, 29, 31, 34 to 37, 69 to 73 and 75 to recite "mammalian" is supported, for example, by originally filed claims 5 and 33, and in the specification, for example, at page 6, line 7 and page 25, lines 2-3. The amendment to claims 6, 7 and 33 was necessitated by the amendment to independent claims 1 and 30 respectively, to recite "mammalian." Accordingly, as the amendments to the claims are supported by the specification or were made in order to address various informalities no new matter has been added and entry thereof is respectfully requested.

Regarding the Declaration

The Examiner maintains that the Oath or Declaration is defective. Applicants respectfully point out that the executed Declaration was filed under 35 U.S.C. 25 and 37 C.F.R. §1.68 and is not a statutory Declaration filed under 28 U.S.C. §1746. Accordingly, as the executed Declaration was filed under 35 U.S.C. 25 and 37 C.F.R. §1.68, and not 28 U.S.C. §1746, the requirements of 28 U.S.C. §1746 do not apply to the Declaration. Consequently, the executed Declaration filed under 35 U.S.C. 25 and 37 C.F.R. §1.68 is not defective and Applicants need not submit a Supplemental Declaration. [see, M.P.E.P. §§602.03 and 602.05]

I. REJECTIONS UNDER 35 U.S.C. §§102(e) and 103(a)

The rejection of claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76 under 35 U.S.C. §102(e) as allegedly anticipated by Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is respectfully traversed. Allegedly, the Declaration under 37 C.F.R. §1.131 executed by the inventors is not of sufficient scope relative to claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76 and in view of Arndt *et al.* In particular, allegedly the Declaration "is limited in scope to evidence of conception to practice of a method using anti-OX40L antibodies to treat asthmatic lung inflammation in a mouse model."

Claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76 are not anticipated by Arndt *et al.* (U.S. Patent Publication No. 2004/0009174). Applicants also respectfully disagree that the Declaration "is limited in scope to evidence of conception to practice of a method using anti-OX40L antibodies to treat asthmatic lung inflammation in a mouse model." To the contrary, the Declaration is commensurate in scope with originally filed claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76.

Nevertheless, solely in order to further prosecution of the subject application, the claims have been amended as set forth above and claims 5, 8, 9, 19, 20 and 32 have been cancelled without prejudice. Applicants will therefore address the rejection as it may relate to the claims upon entry of this paper.

In support of Applicant's position the Declaration is commensurate in scope with claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76, submitted herewith is an executed Declaration under 37 C.F.R. §1.132 (hereinafter the 132 Declaration) by Dr. Linda Bradley, Professor of Immunology at Sidney Kimmel Cancer Center, San Diego, CA. Dr. Bradley is an international expert on T cell memory, the ability of T cells to respond to recall antigens and undergo secondary or recall immune responses.

As stated in the 132 Declaration, Dr. Bradley is familiar with the mouse model used in the studies referred to in the Declarations under 37 C.F.R. §1.131 executed by Dr.s Michael Croft and Shahram Salek-Ardakani and accompanying data (Exhibit A) filed March 23, 2006 (hereinafter the 131 Declaration). Dr. Bradley is also familiar with the data obtained in the studies referred to in the 131 Declaration (see the 132 Declaration, paragraph 2).

Dr. Bradley concludes the following:

1) The mouse model in the studies referred to in the 131 Declaration, in which mice were immunized with a foreign antigen (OVA) and subsequently challenged several weeks later with the same antigen to produce a recall lung inflammatory immune response, was recognized in the art at the time the studies were performed to represent recall immune responses in general, inflammation caused by recall immune responses in general, as well as recall immune responses causing symptoms, such as symptoms associated with a secondary or subsequent immune response including asthma (see the 132 Declaration, paragraph 3).

2) Mice sensitized with OVA followed by a subsequent OVA challenge in a recall response to induce lung inflammation were known to represent recall immune responses and secondary or subsequent immune responses in general at the time the studies were performed. Levels of cytokines, such as IL-4, IFN, IL-5, and IgE were known to reflect whether, and to what extent, a recall immune response was induced. IL-4 and/or IgE levels were known to typically increase in a recall immune response, or secondary or subsequent immune response, in the lung as well as in other tissues and organs such as the spleen and lymph nodes. Neutrophils, eosinophils, monocytes and lymphocytes were also known to reflect whether, and to what extent, a recall immune response was induced. Eosinophils and lymphocytes were known to typically increase in a recall immune response, or secondary or subsequent immune response, in the lung as well as in other tissues and organs (see the 132 Declaration, paragraph 4).

3) The studies in the 131 Declaration show that anti-OX40L antibody reduces IL-4 and IgE levels, as well as numbers of eosinophils and lymphocytes in lung (see the 132 Declaration, paragraph 5).

4) The studies described in the 131 Declaration would be representative of recall immune responses in general, inflammation caused by a recall immune response in general, as well as recall immune responses causing symptoms, such as symptoms associated with a secondary or subsequent immune response including asthma (see the 132 Declaration, paragraph 5).

5) The studies referred to in the 131 Declaration would have been recognized in the art at the time the studies were performed to represent recall immune responses in general, inflammation caused by recall immune responses in general, as well as recall immune responses

causing symptoms, such as symptoms associated with a secondary or subsequent immune response including asthma (see the 132 Declaration, paragraph 6).

Dr. Bradley also concludes the following:

6) The mouse model in the studies referred to in the 131 Declaration was an art recognized model of recall immune responses in mammals in general including humans at the time the studies were performed. Data obtained in the mouse model indicating a reduction or inhibition of a recall immune response, or a reduction or inhibition of one or more symptoms of a secondary or subsequent immune response, would therefore have been known as reasonably correlative to mammals including humans (see the 132 Declaration, paragraph 7).

In view of the 132 Declaration executed by Dr. Linda Bradley, the previously filed 131 Declaration is commensurate in scope with claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76. Consequently, claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 were conceived prior to the December 18, 2001, filing date of the Arndt *et al.* provisional application (serial no. 60/341,453) and therefore, Arndt *et al.* is not available as prior art under 35 U.S.C. §102 or §103(a).

Furthermore, if it is the Patent Office's position that Arndt *et al.* teaches each and every element of the rejected claims even though acknowledging that Arndt *et al.* "is silent about the 'recall' immune response" (see page 7 of the Office Action mailed September 26, 2005), then the Patent Office must accept the 131 Declaration as adequately supporting claims directed to methods of reducing or inhibiting a recall immune response; and methods of alleviating, ameliorating, reducing or inhibiting one or more symptoms associated with a secondary or subsequent immune response to an antigen. In this regard, the Patent Office cannot take the position that Arndt *et al.* teach each and every element of the rejected claims without even mentioning a recall immune response, but then take the position that the 131 Declaration and accompanying data does not support claims encompassing methods of reducing or inhibiting a recall response and is limited to "treat asthmatic lung inflammation in mice." (see page 4 of the Office Action mailed May 26, 2006) To state that Arndt *et al.* teach each and every element of the rejected claims in spite of acknowledging that Arndt *et al.* is "silent about the 'recall' immune response" is completely inconsistent with taking the position that the 131 Declaration and accompanying data are insufficient to support methods of reducing or inhibiting a recall

response. Moreover, Applicants respectfully remind the Patent Office that for the purpose of antedating a reference under Rule 131, it is sufficient that applicant shows a reduction to practice of his *basic invention*, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art. *Emphasis added*; See, *In re Spiller*, 500 F.2d 1170 (CCPA 1974); see, also, M.P.E.P. §715.02.

In view of the foregoing, claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 were conceived prior to the December 18, 2001, filing date of the Arndt *et al.* provisional application (serial no. 60/341,453). Consequently, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §102 or §103(a) against claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

The rejection of claims 1, 8 and 11 under 35 U.S.C. §103(a) as allegedly unpatentable over Arndt *et al.* in view of Owens *et al.* (J. Immunol. Methods 168:149 (1994)) is respectfully traversed. Allegedly, claims 1, 8 and 11 would have been obvious to one of ordinary skill in the art in view of Arndt *et al.* and Owens *et al.*

Claims 1, 8 and 11 would not have been obvious in view of Arndt *et al.* and Owens *et al.* at the time of the invention. For the reasons set forth above, the Declaration under 37 C.F.R. §1.131 filed March 23, 2006 is commensurate in scope with originally filed claims 1, 8 and 11.

Nevertheless, solely in order to further prosecution of the subject application, claims 1 and 11 have been amended as set forth above and claim 8 has been cancelled without prejudice. The rejection of claim 8 is therefore moot. Applicants will therefore address the rejection as it may relate to claims 1 and 11 upon entry of this paper.

First, in terms of claim 11, allegedly human and humanized antibodies would have been obvious over Arndt *et al.* in view of Owens *et al.* Applicants again respectfully direct the Patent Office's attention to *In re Spiller*, 500 F.2d 1170 (CCPA 1974). In *Spiller*, the court stated that for a 131 Declaration, "it is sufficient that appellant has shown a reduction to practice of his basic invention, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art." *Id.* at 1176; see, also, M.P.E.P. §715.02. Thus, in view of *Spiller* the Patent Office cannot reject claim 11 as obvious over Arndt *et al.* in

view of Owens *et al.* and at the same time assert that the 131 Declaration filed March 23, 2006 is of insufficient scope as to claim 11. Consequently, for these reasons alone, the rejection of claim 11 under 35 U.S.C. §103(a) is improper and must be withdrawn.

Secondly, as corroborated by Dr. Linda Bradley and set forth in detail above and in the Declaration under 37 C.F.R. §1.132 submitted herewith, the 131 Declaration filed March 23, 2006 is commensurate in scope with claims 1 and 11. Consequently, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §103(a) against claims 1 and 11. Owens *et al.* (J. Immunol. Methods 168:149 (1994)) fail to teach or suggest each and every element of claims 1 and 11. Accordingly, the rejection of claims 1 and 11 under 35 U.S.C. §103(a) is improper and must be withdrawn.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 03-3975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

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